

STATE OF MICHIGAN
IN THE SUPREME COURT

TAMARA TAYLOR and LEE ANN RINTZ,

Plaintiffs-Appellees

v

A.H. ROBINS COMPANY, INCORPORATED,
WYETH-AYERST LABORATORIES COMPANY,
and AMERICAN HOME PRODUCTS
CORPORATION,

Defendants-Appellants,

and

GATE PHARMACEUTICALS, SMITHKLEIN BEECHAM
CORPORATION, ZENITH GOLDLINE PHARMACEUTICALS,
INC., ABANA PHARMACEUTICALS, INC., RICHWOOD
PHARMACEUTICAL COMPANY, INC., ION LABORATORIES,
INC., MEDEVA PHARMACEUTICALS, INC. INTERNEURON
PHARMACEUTICALS, INC., CAMALL COMPANY, LABORATORIES
SERVIER and ALL MICHIGAN PHYSICIANS WHO PRESCRIBED
OR GAVE FEN-PHEN AND/OR REDUX TO MICHIGAN PATIENTS,

Defendants.

and

JUDITH H. ROBARDS and KENNETH W. ROBARDS,

Plaintiffs-Appellees,

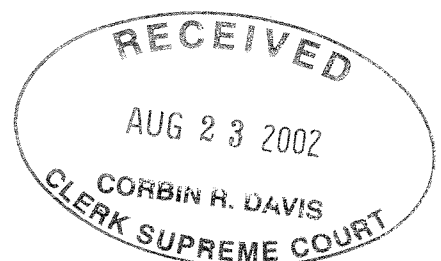
v

A.H. ROBINS COMPANY, INCORPORATED
WYETH-AYERST LABORATORIES COMPANY
and AMERICAN HOME PRODUCTS
CORPORATION,

Defendants-Appellants,

Supreme Court No. 120653
Court of Appeals No. 217269
Consolidated with Nos.
217279, 217290, 217328
Wayne County Circuit Court
Case No. 97-731636-NP
Hon. Marianne O. Battani

Supreme Court No. 120641
Court of Appeals No. 227700
Washtenaw County Circuit Court
Case No. 99-5373-MN
Hon. David S. Swartz



and
JOYCE KAERLE, M.D., and EVELYN ECCLES, M.D.,
GATE PHARMACEUTICALS, SMITHKLINE
BEECHAM CORPORATION, ZENITH GOLDLINE
PHARMACEUTICALS, INC. ABANA
PHARMACEUTICALS, INC., RICHWOOD
PHARMACEUTICALS COMPANY, ION
LABORATORIES, INC., MEDEVA
PHARMACEUTICALS, INC., PARMED
PHARMACEUTICALS, INC., EON LABS
MANUFACTURING, INC. and LES
LABORATORIES SERVIER,

Defendants.

***AMICUS CURIAE* BRIEF OF
THE PRODUCT LIABILITY ADVISORY COUNCIL, INC.
IN SUPPORT OF DEFENDANTS-APPELLANTS' APPEAL**

PROOF OF SERVICE

CLARK HILL PLC
By: James E. Brenner (P11178)
Paul C. Smith (P55608)

500 Woodward Avenue, Suite 3500
Detroit, MI 48226-3435
(313) 965-8300

Hugh F. Young, Jr., Esq.
Product Liability Advisory Council, Inc.
1850 Centennial Park Drive, Suite 510
Reston, VA 20191
(703) 264-5300
Of Counsel
Attorneys for The Product Liability
Advisory Council, *Amicus Curiae*

Dated: August 22, 2002

TABLE OF CONTENTS

| | <u>Page</u> |
|--|-------------|
| INDEX OF AUTHORITIES | iv |
| STATEMENT OF QUESTION INVOLVED | ix |
| INTEREST OF <i>AMICUS CURIAE</i> | 1 |
| STATEMENT OF MATERIAL PROCEEDINGS AND FACTS | 3 |
| Procedural History | 3 |
| The Drugs At Issue | 4 |
| The Wayne County Circuit Court's Decision | 5 |
| The Court of Appeals' Decision | 6 |
| SUMMARY OF ARGUMENT | 8 |
| ARGUMENT | 10 |
| I. A STRONG PRESUMPTION OF CONSTITUTION- ALITY ATTACHES TO SECTION 2946(5) | 10 |
| A. A STATUTE IS PRESUMED TO BE CON- STITUTIONAL ABSENT A SHOWING THAT NO SET OF CIRCUMSTANCES EXISTS UNDER WHICH THE STATUTE WOULD BE VALID | 10 |
| B. SECTION 2946(5) RESULTED FROM THE MICHIGAN LEGISLATURE'S DELIBERATE EXERCISE OF ITS CONSTITUTIONAL AUTHORITY TO LEGISLATE | 12 |

| | |
|---|----|
| 1. LEGAL COMMENTATORS HAVE LONG SUPPORTED THE SAFE HARBOR CONCEPT OF REGULATORY COMPLIANCE AS A DEFENSE TO PRODUCT LIABILITY CLAIMS | 12 |
| 2. THE AMERICAN LAW INSTITUTE HAS RECOMMENDED THE ESTABLISHMENT OF A REGULATORY COMPLIANCE DEFENSE | 13 |
| 3. BECAUSE OF THE FDA'S EXPERTISE AND THE THOROUGHNESS OF ITS PROCEDURES, FDA APPROVAL IS ENTITLED TO PARTICULAR DEFERENCE | 16 |
| 4. IN AN EARLIER CASE, DECIDED BY THIS COURT WHEN THE PREDECESSOR STATUTE TO SECTION 2946(5) WAS IN EFFECT, THE COURT'S DECISION SUGGESTED THAT THE LEGISLATURE COULD HAVE MADE GOVERNMENTAL STANDARDS CONCLUSIVE IN PRODUCTS LIABILITY ACTIONS, INSTEAD OF MERELY ADMISSIBLE IN EVIDENCE | 19 |
| 5. THE INCORPORATION OF FDA APPROVAL AS AN EXTRINSIC STANDARD IN STATE STATUTES IS NEITHER EXTRAORDINARY NOR IMPERMISSIBLE | 20 |
| 6. SECTION 2946(5) IS A KEY PART OF THE LEGISLATURE'S REFORM OF PRODUCT LIABILITY LAW IN MICHIGAN, AND AN APPROPRIATE EXERCISE OF LEGISLATIVE AUTHORITY | 22 |
| II. IT WAS ERROR FOR THE COURT OF APPEALS TO HOLD THAT PLAINTIFFS OVERCAME THE STRONG PRESUMPTION OF CONSTITUTIONALITY ATTACHING TO SECTION 2946(5) | 25 |
| A. THE COURT OF APPEALS RECOGNIZED, BUT THEN IGNORED THE STRONG PRESUMPTION OF CONSTITUTIONALITY ATTACHING TO SECTION 2946(5) | 25 |

| | |
|--|----|
| B. LIKE THE WAYNE COUNTY CIRCUIT COURT, THE COURT OF APPEALS ERRED IN ITS RELIANCE UPON THE <i>COFFMAN</i> AND THE <i>COLONY TOWN CLUB</i> CASES | 26 |
| C. THE COURT OF APPEALS' RELIANCE ON THE <i>DEARBORN INDEPENDENT</i> AND THE <i>RADECKI</i> CASES IS LIKEWISE MISPLACED | 28 |
| D. THE COURT OF APPEALS ACKNOWLEDGED THE DOCTRINE OF INDEPENDENT SIGNIFICANCE, BUT ADDED TO IT AN INSUPPORTABLE QUALIFICATION | 30 |
| E. THE COURT OF APPEALS ADVANCED NO BASIS IN ITS OPINION SUFFICIENT TO OVERCOME THE STRONG PRESUMPTION OF CONSTITUTIONALITY ATTACHING TO SECTION 2946(5). | 32 |
| CONCLUSION AND RELIEF REQUESTED | 33 |

INDEX OF AUTHORITIES

| <u>Cases</u> | <u>Page(s)</u> |
|---|----------------|
| <i>Carmichael v Southern Coal Co</i> , 301 US 495; 57 S Ct 868, 81 L Ed 1245 (1937) | 10 |
| <i>Caterpillar, Inc. v Dep't of Treasury</i> , 440 Mich 400; 488 NW2d 182 (1992) | 11 |
| <i>Coffman v State Board of Examiners</i> , 331 Mich, 582; 50 NW2d 322 (1951) | 26,27,31 |
| <i>Colony Town Club v Michigan Unemployment Compensation Comm'n</i> , 301 Mich 107; 3 NW2d 28 (1942) | 25,27,31 |
| <i>Council of Organizations & Others for Ed About Parochiaid, Inc.</i> <i>v Governor</i> , 445 Mich 557; 566 NW2d 209 (1997) | 10,11 |
| <i>Daroma v Glazer</i> , No. 99-017501 | 3 |
| <i>Dearborn Independent, Inc v City of Dearborn</i> , 331 Mich 447; 49 NW2d 370 (1951) | 27,28,31 |
| <i>Donajkowski v Alpena Power Co</i> , 460 Mich 243; 596 NW2d 574 (1999) | 26 |
| <i>Dyke v Richard</i> , 390 Mich 739 (1973) | 6,24 |
| <i>Field v Clark</i> , 143 U.S. 649 (12 Sup. Ct. 495) | 29 |
| <i>Grand Rapids v Consumers Power Co</i> , 216 Mich 409; 185 NW 852 (1921) | 1 |
| <i>Hett v Duffy</i> , 346 Mich 456; 78 NW2d 284 (1956) | 26 |
| <i>In re Hamlet (After Remand)</i> , 225 Mich App 505; 571 NW2d 750 (1997) | 11 |

| | |
|--|----------|
| <i>Johnson v Harnischfeger Corp,</i> 414 Mich 102; 323 NW2d 912 (1982) | 10 |
| <i>Lehnhausen v Lake Shore Auto Parts Co,</i> 410 US 356; 93 S Ct 1001, 35 L Ed2d 351 (1973) | 10 |
| <i>Mahaffey v Attorney General,</i> 222 Mich App 325; 564 NW2d 104 (1997) | 11 |
| <i>McDonald v Kambhampati,</i> No. 99-018449 | 3 |
| <i>McDougall v Schanz,</i> 461 Mich 15; 597 NW2d 148 (1999) | 10,24 |
| <i>Michigan Baptist Homes and Development Co v City of Ann Arbor,</i> 55 Mich App 725; 223 NW2d 324 (1974), <i>aff'd</i> , 396 Mich 660; 242 NW2d 749 (1976) | 30,31,32 |
| <i>Neal v Oakwood Hosp Corp,</i> 226 Mich App 701; 575 NW2d 68 (1997) | 11 |
| <i>O'Brien v Hazelett & Erdal,</i> 410 Mich 1; 299 NW2d 336 (1980) | 24 |
| <i>Owens v Allis-Chalmers Corp,</i> 414 Mich 413; 326 NW2d 372 (1982) | 19 |
| <i>People v Bricker,</i> 389 Mich 524; 208 NW2d 172 (1972) | 10 |
| <i>Radecki v Director of Bureau of Worker's Disability Compensation,</i> 208 Mich App 19; 526 NW2d 611 (1994) | 28,29,32 |
| <i>State v Kellogg,</i> 98 Idaho 541; 568 P2d 514 (1977) | 22 |
| <i>Tribbett v Marcellus,</i> 294 Mich 607, 615; 293 NW 872 (1940) | 30 |
| <i>United States v Salerno,</i> 481 US 739; 107 S Ct 2095, 95 L Ed2d 697 (1987) | 10,11 |

| | |
|---|----------|
| Mont[ana] Code Ann, § 50-6-601(1)(a) | 21 |
| Neb[raska] Rev Stat § 71-356.05 | 21 |
| Nev[ada] Rev Stat § 639.2597 | 21 |
| N[ew] Y[ork] Educ Law § 7101-a(10)(b) | 21 |
| Ohio Rev Code Ann § 2925.06 | 21 |
| Tenn[essee] Code Ann § 53-14-102 | 21 |
| Tex[as] Health & Safety Code § 431.02(z) | 21 |
| V[ermon]t Stat Ann § 4601(4) | 21 |
| W[est] V[irgini]a Code § 16-4-24 | 21 |
| 21 U.S.C. 301-397 (1997), Federal Food, Drug and Cosmetic Act | 16,17,23 |

Constitutions

| | |
|--|------|
| Article 3, §7 of the Michigan Constitution of 1963 | 6,24 |
|--|------|

Miscellaneous

| | |
|---|----|
| American Law Institute “Reporters’ Study on Enterprise Responsibility for Personal Injury” | 14 |
| James A. Henderson, Jr. & Aaron D. Twerski, “Doctrinal Collapse In Products Liability: The Empty Shell Of Failure To Warn”, 65 N.Y.U.L. Rev. 265, 321 (1990) | 13 |
| John P. Raleigh, “The ‘State Of The Art’ In Product Liability: A New Look At An Old ‘Defense,’” 4 Ohio N.U.L. Rev. 249, 261 (1977) | 12 |
| Michael D. Green, “Statutory Compliance And Tort Liability: Examining The Strongest Case”, 30 U. Mich. J. L. Ref. 461 (1997) | 18 |
| Paul Dueffert, “The Role Of Regulatory Compliance In Tort Actions”, 26 Harv. J. Legis. 175 (1989) | 16 |

Richard A. Epstein, "Legal Liability For Medical Innovation", 8 Cardozo L. Rev. 1139, 1151 (1987) 12

Richard C. Ausness, "The Case For A 'Strong' Regulatory Compliance Defense", 53 Md. L. Rev. 1210 (1996) 13

Senate Fiscal Agency Bill Analysis 22

STATEMENT OF QUESTION INVOLVED

Where the Michigan Legislature through the exercise of its legislative authority has determined that FDA approval of drugs provides an appropriate extrinsic standard to use in defining the limits of product liability for manufacturers and sellers of drugs in Michigan, and has embodied that determination in a statute, and where a strong presumption of constitutionality attaches to statutes generally, does this statute - MCL 600.2946(5); MSA 27A.2946(5) - represent an unconstitutional delegation of legislative authority to the FDA?

The Wayne County Circuit Court answered: "Yes."

The Circuit Courts of Oakland and Washtenaw Counties answered: "No."

The Court of Appeals answered: "Yes."

Defendants-Appellants answer: "No."

Your *amicus curiae*, The Product Liability Advisory Council, Inc., answers: "No."

INTEREST OF *AMICUS CURIAE*

The Product Liability Advisory Council, Inc., ("PLAC") is a nonprofit association with 122 corporate members representing a broad cross-section of American industry. Its corporate members include manufacturers and sellers in a wide range of industries, from automobiles to electronics to pharmaceutical products. A list of PLAC's current corporate membership is attached as Appendix A. In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (i.e., non-voting) members of PLAC.

PLAC's primary purpose is to file *amicus curiae* briefs in cases with issues that affect the development of product liability law and have potential impact on PLAC's members. PLAC has submitted numerous *amicus curiae* briefs in both state and federal courts, including this Court.¹

The issue before the Court – the constitutionality of MCL 600.2946(5); MSA 27A.2946(5) ("Section 2946(5)"), a provision limiting the liability of manufacturers and sellers of FDA-approved drugs in Michigan product liability actions – is of paramount significance to PLAC's membership. It is an issue that stands at the cutting edge of the development of product liability law in the United States. PLAC seeks to assist the Court by highlighting the impact this case may have beyond the immediate concerns of the parties to this case. Because of its experience in these matters, PLAC believes itself well situated to brief the Court on the concerns of the business community and the significance of this case to PLAC's members.

¹ It has long been the policy in this State to grant leave to file *amicus* briefs in cases "involving questions of important public interest" because the Court "is always desirous of having all the light it may have on the questions before it." *Grand Rapids v Consumers Power Co*, 216 Mich 409, 415; 185 NW 852 (1921). On July 2, 2002, this Court granted PLAC's motion to file a brief *amicus curiae*.

As the American Law Institute has suggested, subjecting pharmaceutical products to a system of comprehensive regulation followed by litigation imposes a disproportionate burden, which causes overdeterrence in the development of these products. FDA approval is based on a comprehensive and careful determination that the risks, if any, of a particular pharmaceutical product are reasonable in light of the health benefits it provides. The Michigan Legislature has determined that FDA approval conclusively establishes the standard of care a manufacturer or supplier owes to its customers and precludes tort liability. PLAC respectfully submits that Section 2946(5) not only falls within the power of the Michigan Legislature, but constitutes practical and beneficial legislation which will assist the development and availability of life-saving pharmaceutical products.

STATEMENT OF MATERIAL PROCEEDINGS AND FACTS

As its Statement of Material Proceedings and Facts, your *amicus curiae* adopts the Concise Statement of Material Proceedings and Facts of Defendants-Appellants. Those facts particularly pertinent to the issues discussed in this brief are summarized below.

Procedural History

This is a set of product liability actions where Plaintiffs, “on behalf of themselves and all others similarly situated,” allege personal injury from the use of the drugs fenfluramine, phentermine, and dexfenfluramine, which are FDA-approved pharmaceuticals. Defendants-Appellants sought dismissal of the complaints on the basis of Michigan law providing that a manufacturer or seller of a drug is not liable in a products liability action if the drug was approved by the FDA and both the drug and its labeling were in compliance with that approval at the time the drug left the control of the manufacturer or seller. In *Taylor*, the Wayne County Circuit Court denied defendants-appellants’ motion after a hearing on September 11, 1998, pursuant to an opinion entered on November 24, 1998, and an order entered on January 8, 1999. The court indicated in its opinion that it would stay the action pending appellate determination of the constitutionality of the statute. In *Robards*, the Washtenaw County Circuit Court found Section 2946(5) constitutional, and entered its order on April 12, 2000, granting defendant-appellants’ motion for summary disposition.²

²In *McDonald v Kambhampati*, No. 99-018449, and *Daroma v Glazer*, No. 99-017501, the Oakland County Circuit Court also upheld the constitutionality of Section 2946(5). Those cases are not part of this appeal.

The Court of Appeals consolidated the *Taylor* and the *Robards* cases on appeal, and issued a single opinion. In its opinion the Court of Appeals found Section 2946(5) to be an unconstitutional delegation of legislative authority, affirming the summary disposition order of the Wayne County Circuit Court in *Taylor* and reversing the order of the Washtenaw County Circuit Court in *Robards*.

By its orders dated July 2, 2002, this Court granted defendants-appellants leave to appeal from this order of the Court of Appeals. Your *amicus curiae* files this brief in support of defendants-appellants' appeal.

The Drugs At Issue

The term "Fen-Phen" comes from unauthorized slang usage referring to a combined use of two different drugs used in the treatment of obesity; those drugs are generically known as fenfluramine hydrochloride and phentermine hydrochloride. The third drug involved in this matter, dexfenfluramine hydrochloride, is a derivative of fenfluramine hydrochloride. No product on the market ever contained both fenfluramine and phentermine in a single tablet or capsule.

It is uncontested below that the FDA had approved the challenged drugs and their labeling before these drugs left the control of any Defendant. Phentermine hydrochloride remains on the market. Defendant-Appellant Smithkline sold phentermine hydrochloride under the brand name Fastin®, which was approved for safety and efficacy by the FDA in 1973. Neither Fastin®, nor phentermine hydrochloride generally, have been deemed by the FDA to be

unsafe. Fenfluramine hydrochloride and dexfenfluramine hydrochloride (the generic name for Redux®) were voluntarily withdrawn from the market in 1997.

The Wayne County Circuit Court's Decision

Defendants-Appellants filed motions for summary disposition in Wayne County Circuit Court contending that the complaint should be dismissed with prejudice since Plaintiffs' claims were unenforceable pursuant to the provisions of Section 2946(5). In response, Plaintiffs admitted that the drugs at issue were labeled in compliance with FDA requirements and that the Plaintiffs had not pled any of the statutory exceptions to Section 2946(5). Plaintiffs nevertheless asserted that Section 2946(5) impermissibly delegated judicial and legislative authority, improperly denied access to the courts, and violated equal protection and due process guarantees. Plaintiffs also requested that the entire 1995 Tort Reform Act, 1995 PA 161 and 1995 PA 249, be struck if Section 2946(5) were found unconstitutional .

The Wayne County Circuit Court denied all of Plaintiffs' claims except one, the claim that Section 2946(5) unconstitutionally delegates legislative authority.³ In denying Plaintiffs' claim that Section 2946(5) was an unconstitutional delegation of **judicial** power, the Wayne County Circuit Court appeared to prepare the way for the same outcome as to the claim of unconstitutional delegation of **legislative** power:

While a decision by the FDA effectively requires a court to dismiss a case, it should be noted that the statute does not, in fact, involve the FDA in judicially reviewing a products liability claim. Indeed, contrary to plaintiffs' suggestion,

³In the Court of Appeals, Plaintiffs cross-appealed the right of access to courts, equal protection, and due process issues. The Court of Appeals left the rulings of the Wayne County Circuit Court undisturbed as to those issues. Accordingly, this *amicus curiae* brief does not discuss those issues.

FDA approval cannot be equivalent to the situation in Knoke, because the statute does not address the powers of the judge. Also, the statute provides a number of exceptions. Hence, FDA approval may not be determinative of the merits of the case. In any event, under the statute, the court must still review the matter to ensure that the case falls within the provision of the statute, and is not governed by any of the exceptions.

Finally, it is competent for the legislature to change the common law and even completely abrogate common law causes of action. Const 1963, art 3 §7. As held in Dyke v Richard, 390 Mich 739, 745 (1973), "A statute which expressly extinguishes a common law right may be regarded as a proper exercise of legislative authority." Because Section 2946(5) does not involve the direct delegation by the legislature to the FDA of judicial powers to review the merits of the case, it is distinguishable from the court rule under consideration in Knoke.

Opinion at p. 5. The Wayne County Circuit Court's reasoning on why Section 2946(5) is not an unconstitutional delegation of judicial authority would seem to apply equally to why the statute also is not an unconstitutional delegation of legislative authority. Nevertheless, the court inexplicably held the statute constitutional against the one challenge and unconstitutional against the other.

The Court of Appeals' Decision

Essentially, the Court of Appeals followed the reasoning of the Wayne County Circuit Court. Near the end of its opinion the Court of Appeals addressed "defendants' most detailed and seemingly compelling argument in favor of finding MCL 600.2946(5) constitutional," namely, the doctrine of independent significance. But then, despite the fact that this Court has upheld the doctrine, the Court of Appeals chose not to follow "this almost convincing argument." Opinion, p. 10.

Defendants-appellants' argument based upon the "independent significance" doctrine was convincing, and not merely "almost" so. The Court of Appeals opinion to the contrary does not withstand scrutiny.

SUMMARY OF ARGUMENT

Defendants-appellants' appeal asks this Court to review and reverse the Court of Appeals' decision which declares Section 2946(5) unconstitutional. The Michigan Legislature did not "delegate" its legislative authority to the FDA – that is to say, it did not improperly confer on the FDA the Legislature's exclusive power to make laws governing the State of Michigan. Rather, the Michigan Legislature, in the exercise of its exclusive constitutional power to make Michigan law, determined that FDA approval of drugs was an appropriate extrinsic standard to use in defining the limits of product liability (i.e., the standard of care) for manufacturers and sellers of drugs in Michigan.

A strong presumption of constitutionality attaches to Section 2946(5). Generally a statute is presumed constitutional absent a showing that no set of circumstances exists under which the statute would be valid. Here, Section 2946(5) resulted from the Legislature's deliberate exercise of its constitutional authority to legislate. Legal commentators and the American Law Institute have long supported establishment of a regulatory compliance defense. Given the FDA's expertise and the thoroughness of its procedures, FDA approval is entitled to particular deference. An earlier decision of this Court suggests the Legislature could give conclusive effect to governmental standards in product liability actions. Enactment of Section 2946(5) was an appropriate exercise of legislative authority.

The Court of Appeals committed error in holding that plaintiffs overcame the strong presumption of constitutionality attaching to Section 2946(5). It recognized but ignored the presumption of constitutionality. It relied on cases which it either misconstrued or misapplied.

Though acknowledging the doctrine of independent significance, the Court of Appeals attempted to add to the doctrine a qualification which proved insupportable. Moreover, the qualification itself would support constitutionality of Section 2946(5). The reasons advanced by the Court of Appeals do not overcome the strong presumption of constitutionality attaching to Section 2946(5).

ARGUMENT

I. A STRONG PRESUMPTION OF CONSTITUTIONALITY ATTACHES TO SECTION 2946(5).

A. A STATUTE IS PRESUMED TO BE CONSTITUTIONAL ABSENT A SHOWING THAT NO SET OF CIRCUMSTANCES EXISTS UNDER WHICH THE STATUTE WOULD BE VALID.

A statute is presumed constitutional absent a clear showing to the contrary. *Lehnhausen v Lake Shore Auto Parts Co*, 410 US 356; 93 S Ct 1001, 35 L Ed2d 351 (1973); *People v Bricker*, 389 Mich 524, 528; 208 NW2d 172 (1973); *Johnson v Harnischfeger Corp*, 414 Mich 102, 112; 323 NW2d 912 (1982); and *McDougall v Schanz*, 461 Mich 15, 24; 405 NW2d 148 (1999).

In *Lehnhausen v Lake Shore Auto Parts Co*, *supra*, the United States Supreme Court quoted with favor from *Carmichael v Southern Coal Co*, 301 US 495; 57 S Ct 868, 81 L Ed 1245 (1937), noting that a "state legislature, in the enactment of laws, has the widest possible latitude within the limits of the Constitution" and that "courts cannot assume that [the legislature's] action is capricious, or that, with its informed acquaintance with the local conditions to which the legislation is to be applied, it was not aware of facts which afford reasonable basis for its action." 410 US at 364-365.

This Court, in *Council of Organizations v Governor*, 455 Mich 557, 568; 566 NW2d 208 (1997), quoting *United States v Salerno*, 481 US 739; 107 S Ct 2095, 95 L Ed2d 697 (1987), reaffirmed with unequivocal language the strong presumption of constitutionality attaching to statutory enactments by the Legislature:

The party challenging the facial constitutionality of an act "must establish that no set of circumstances exists under which the [a]ct would be valid. The fact that the . . . [a]ct might operate unconstitutionally under some conceivable set of circumstances is insufficient" *Salerno, supra* at 745. "[I]f any state of facts reasonably can be conceived that would sustain [a legislative act], the existence of the state of facts at the time the law was enacted must be assumed." 16 Am Jur 2d, Constitutional Law, §218, p. 642.

455 Mich at 568-569.

In *Neal v Oakwood Hosp Corp*, 226 Mich App 701; 575 NW2d 68 (1997), the Court of Appeals, citing to *Council of Organizations v Governor, supra*, emphasized the constitutional deference afforded to statutes, observing that the "power to declare a law unconstitutional should be exercised with extreme caution and never where a serious doubt exists with regard to the conflict. " 226 Mich App at 723.

The Court of Appeals in the instant case left no doubt of its awareness of the presumption of constitutionality attaching to statutes:

Statutes are presumed to be constitutional, and courts have a duty to construe a statute as constitutional unless its unconstitutionality is clearly apparent. *Caterpillar, Inc. v Dep't of Treasury*, 440 Mich 400, 413; 488 NW2d 182 (1992); *Mahaffey v Attorney General*, 222 Mich App 325, 344; 564 NW2d 104 (1997). The party asserting the constitutional challenge has the burden of proving the law's invalidity. *In re Hamlet (After Remand)*, 225 Mich App 505, 521-522; 571 NW2d 750 (1997). A party challenging the facial constitutionality of a statute must establish that no circumstances exist under which it would be valid. *Council of Organizations & Others for Ed About Parochiaid, Inc. v Governor*, 455 Mich 557, 568; 566 NW2d 208 (1997).

Opinion, p. 7.

**B. SECTION 2946(5) RESULTED FROM THE
MICHIGAN LEGISLATURE'S DELIBERATE
EXERCISE OF ITS CONSTITUTIONAL
AUTHORITY TO LEGISLATE.**

**1. LEGAL COMMENTATORS HAVE
LONG SUPPORTED THE SAFE
HARBOR CONCEPT OF REGULA-
TORY COMPLIANCE AS A DEFENSE
TO PRODUCT LIABILITY CLAIMS.**

A sampling from legal commentary over three decades shows continuing support for the regulatory compliance defense. In 1977, for instance, John R. Raleigh, advocated adoption of the regulatory compliance defense, declaring:

... It is patently absurd that the machinery of governmental standard setting should be observed through vigorous procedures , and that designers should be required to meet the mark of that standard, only to have their design second guessed and their responsibilities expanded case by case....⁴

Ten years later, Richard A. Epstein no less forcefully called for a "rule that provides that certain warnings approved by, say, the FDA, shall be conclusively regarded as adequate in any subsequent lawsuit."⁵ After noting that no administrative process is "ideal," he explained the need for such a rule:

... Indeed, the FDA has been highly criticized because of its conservative approach to the release of new drugs on the market. Nonetheless, if we are prepared to trust to the agency the basic decision of whether or not the drug will be marketed, then it seems odd to say that it cannot confront, with an assist from the medical profession, the warning issue as well. Warnings and package inserts

⁴John P. Raleigh, "The 'State of the Art' In Product Liability: A New Look At An Old Defense," 4 Ohio N.U.I. Rev. 249, 261 (1977).

⁵Richard A. Epstein, "Legal Liability for Medical Innovation," 8 Cardozo L. Rev. 1139, 1151-1152 (1987).

are already required by the FDA, so the critical point is only to provide the firms safe harbor when they comply with the demands of the statute....⁶

The support did not wane in the nineteen-nineties. James A. Henderson, Jr., and Aaron D. Twerski, for example, at the decade's beginning, urged that "Courts recognizing the limits of an institutional capability should refuse to second-guess the judgments of agencies who possess not only expertise but also a capacity for knowledge and memory which the courts cannot match."⁷ In 1996, Richard C. Ausness remarked that a regulatory compliance defense "must fully protect manufacturers from liability when their products meet applicable federal design, testing, or labeling requirements" and "must also provide immunity to manufacturers whose products have satisfied federal requirements for premarket licensing or approval."⁸

2. THE AMERICAN LAW INSTITUTE HAS RECOMMENDED THE ESTABLISHMENT OF A REGULATORY COMPLIANCE DEFENSE.

The American Law Institute was organized in 1923 following a study conducted by a group of prominent American judges, lawyers and teachers known as "The Committee on the Establishment of a Permanent Organization for the Law". The Institute's charter stated its purpose to be "to promote the clarification and simplification of the law and its better adaption to social needs, to secure the better administration of justice, and to encourage and carry on scholarly and scientific legal work." Its incorporators included Chief Justice and former

⁶Id.

⁷James A. Henderson, Jr. and Aaron D. Twerski, "Doctrinal Collapse In Product Liability: The Empty Shell Of Failure To Warn," 65 N.Y.U.L. Rev. 265, 321 (1990).

⁸Richard C. Ausness, "The Case For A 'Strong' Regulatory Compliance Defense," 53 Md. L. Rev. 1210, 1253 (1996).

President William Howard Taft, future Chief Justice Charles Evans Hughes, and former Secretary of State, Elihu Root; Judge Benjamin N. Cardozo and Learned Hand were among its early leaders.⁹

The Institute's By-Laws authorize an elected membership of 3,000 consisting of judges, lawyers, and law teachers from all areas of the United States as well as some foreign countries, selected on the basis of professional achievement and demonstrated interest in the improvement of the law. The Institute engages in intense examination and analysis of legal areas thought to need reform, generally culminating in a work product containing extensive recommendations or proposals for change in the law. In 1991 the Institute published the "Reporters' Study on Enterprise Responsibility for Personal Injury" (hereinafter "ALI Study"). One of the questions considered in the ALI Study was whether a given activity that is subject to and complies with regulatory controls, should also be subject to liability. The ALI Study noted that subjecting enterprise activities to a double set of remedial controls creates dangers of over deterrence:

... Recent experience with vaccines, birth control products, small aircraft, and hazardous waste management indicates that the legal system has deterred enterprises from undertaking certain lines of activity that are socially beneficial....¹⁰

The ALI Study found that the growing concern over potential over deterrence resulting from imposing tort liability on regulated products and activities has resulted in legislation to change the traditional rule that regulatory compliance is not a defense to liability, noting that several states, including Colorado, Kansas, North Dakota, Tennessee, and Utah have enacted

⁹ *About The American Law Institute*, www.ali.org/ali/thisali.htm (visited 3/6/2002). Among other things, the ALI publishes the Restatements of the Law.

¹⁰ ALI Study, Vol. II at 86.

statutes making regulatory compliance presumptive evidence of proper conduct, with New Jersey having such a statute for FDA-approved drugs and drug labels.¹¹ The ALI Study then stated as follows:

We believe that the risk of over deterrence of socially valuable activities through imposition of tort liability on regulated products and activities merits more widespread recognition of a regulatory compliance defense.¹²

Finally, the ALI Study recommended establishment of a regulatory compliance defense which provides that compliance with regulatory requirements imposed by an administrative agency precludes tort liability.¹³ The recommended defense would be subject to three conditions. First, the risk must have been placed under regulatory control by a specialized administrative agency with statutory authority to monitor and assess risk-creating activities in its area of responsibility and with a mandate to establish and revise regularly specific regulatory controls on enterprise behavior. Second, the enterprise in question must have complied with all relevant regulatory requirements. Third, the enterprise must have disclosed to the relevant regulatory agency any material and information in its possession regarding risks.

The ALI Study recommended that such a defense would not have a very extensive application but, rather, would apply primarily to closely regulated products. The products mentioned included pharmaceuticals.

¹¹ *Id.* at 90 noting Colo. Rev. Stat. §13-21-403 (1987); Kan. Stat. Ann. §60-3304 (1983 & Supp. 1987); N. Dakota Code §25-01.1-05(3); Tenn. Code Ann. §29-28-104 (1978 & Supp. 1987); Utah Judicial Code §78-15-6(3); N.J. Code §2A:58C-4 (1987).

¹² ALI Study, Vol. II at 95.

¹³ *Id.* at 95-101.

3. BECAUSE OF THE FDA'S EXPERTISE AND THE THOROUGHNESS OF ITS PROCEDURES, FDA APPROVAL IS ENTITLED TO PARTICULAR DEFERENCE.

The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301-397 (1997) authorizes the FDA to regulate the development, production, testing and labeling of drugs. The FDA must license new drugs before they can be marketed. This licensing process begins with the submission of an Investigational New Drug (IND) application and if the IND application is approved, the manufacturer is then allowed to prepare a formal New Drug Application (NDA). The NDA must contain all information that is known about the drug at the time of the application. Prior to licensing, experts review the data in the NDA and determine that the drug is safe and effective for its intended purpose. The FDA has comprehensive regulatory authority over drug formulation, production, testing and labeling and is the sole decision maker concerning the safety of drugs marketed in the United States.

In 1989 Paul Dueffert, writing in the *Harvard Journal on Legislation*, observed that pharmaceuticals provide an example where "tort reform legislation should create a strong presumption of non-negligence for manufacturers such as those selling FDA-approved drugs."¹⁴ He followed this observation with a demonstration of the language which might be used to state the categorical exclusion. It contains many of the elements found in Section 2946(5):

If a claimant alleges in a product liability claim that a drug caused harm to him or her, the manufacturer of the drug shall be deemed to have acted reasonably and in a manner not negligent in connection with that product liability claim if the drug that allegedly caused the harm was manufactured and

¹⁴Paul Dueffert, "The Role of Regulatory Compliance In Tort Actions," 26 Harv. J. on Legis. 175, 223 (1989).

labelled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U.S.C. 301-392, as amended, or the Public Health Service Act, 58 Stat. 682, 42 U.S.C. 201-300 cc-15, as amended, unless it is established, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type.¹⁵

According to Dueffert, the unwillingness of courts to defer to the judgment of the FDA in areas of drug labelling and composition is unwarranted. Regarding the competence of the FDA to balance societal benefits derived from the use of a drug against attendant safety risks, Duffert did not mince his words:

The FDA simply knows more – it benefits from the expertise of a trained and experienced staff as well as from its careful and well-organized processes for evaluating the efficacy of proposed drugs. And although the FDA exercises authority over numerous products, each drug is fungible and thus possesses nothing akin to the unforeseeable ‘extraordinary hazards’ which in the past have been doctrinally required to subject a defendant to tort liability. Furthermore, the FDA is intimately familiar with the unique drug distribution network and the special role that doctors and pharmacists play in both advising patients regarding harmful side-effects and in limiting public access to drugs. In such an environment, lay opinions as to the reasonableness of product labeling are likely to be misguided. Finally, the FDA enjoys a powerful statutory mandate to prevent unsafe pharmaceuticals from reaching the marketplace; the actions of courts in assessing tort liability against manufacturers would seem merely to duplicate the role. Therefore, the case against dual control of pharmaceutical production by both the FDA and the tort system seem strong indeed. Only where a manufacturer has defrauded the FDA, or has through negligence misproduced a drug so as to materially differ from the

¹⁵Id.

FDA-approved composition, should a drug manufacturer be subject to tort liability.¹⁶

Even the source cited and relied upon by plaintiffs in their brief to the Court of Appeals acknowledges the special expertise and thoroughness of the FDA's drug-approval process. In "Statutory Compliance And Tort Liability: Examining The Strongest Case," 30 *U.Mich. J.L. Ref.* 461 (1997), Michael D. Green conceded the special competence of the FDA and the powerful thrust of product liability law reform centered on the FDA approval defense:

There are several reasons for scrutinizing prescription drugs and the FDA. First, the prescription drug industry is the most heavily regulated industry (for safety purposes) in this country today. The United States leads other Western countries in its vigilance in protecting its citizenry from the risks of prescription drugs; indeed, the FDA has been criticized severely for its overprotectiveness of the populace. Unlike many other regulatory contexts, the FDA extensively regulates drugs from cradle to grave, and it is difficult to identify areas of potential risk reduction that the FDA does not address in its regulations. Indeed, as explained below, the vast majority of products liability litigation concerns the provision of warnings and information about safe use of drugs, a major area of FDA regulation. In short, pharmaceuticals... are the strongest case for accepting governmental safety standards as conclusive when an injured plaintiff sues a pharmaceutical manufacturer for iatrogenic injuries allegedly caused by a pharmaceutical.

Second, the matter of a statutory compliance defense for the pharmaceutical industry comprises quite a prominent aspect of contemporary tort reform legislation. Partially as a consequence of the vigor of FDA regulation and partially as a consequence of the perceived socially detrimental effects of the present system of products liability law and its application to prescription drugs, there has been a great deal of contemporary activity and interest in changing the effect of FDA approval or compliance in products liability litigation. Several states have enacted statutes providing [as examples, Green refers in a footnote to Michigan, New Jersey, Ohio, Oregon, and Utah], a number of commentators have advocated, and Congress has considered seriously special treatment of pharmaceuticals and other products regulated by the FDA. The basic thrust of this legislative reform would be to insulate manufacturers of pharmaceuticals approved by the FDA or manufacturers who comply with applicable FDA

¹⁶Id. at 209 (footnotes omitted).

regulations from tort liability, or, alternatively, from liability for punitive damages.¹⁷

Contrasting the FDA with a common law jury, Green admits:

... it seems plain that the FDA, with its expertise, can reach more accurate decisions than can a common law jury. Even the most vociferous critics of a regulatory compliance defense do not argue otherwise.¹⁸

4. IN AN EARLIER CASE, DECIDED BY THIS COURT WHEN THE PREDECESSOR STATUTE TO SECTION 2946(5) WAS IN EFFECT, THE COURT'S DECISION SUGGESTED THAT THE LEGISLATURE COULD HAVE MADE GOVERNMENTAL STANDARDS CONCLUSIVE IN PRODUCTS LIABILITY ACTIONS, INSTEAD OF MERELY ADMISSIBLE IN EVIDENCE.

This Court decided *Owens v Allis-Chalmers Corp* in 1982.¹⁹ At the time, the Michigan Legislature had recently enacted MCL 600.2946; MSA 27A.2946, regarding which the Court said:

We note that our Legislature has recently enacted a statute which provides that industrial and governmental standards are admissible in products liability actions, MCL 600.2946; MSA 27A.2946. The statute does not provide that such standards are conclusive....

The logical implication of this language is that the Michigan Legislature could have made the standards conclusive at the time, though in fact it chose not to do so. Moreover, the weight of a presumption should not make a difference in the constitutional inquiry, since enactment of something less than a conclusive presumption would seem to be the same as enacting a

¹⁷Green, at 463-465.

¹⁸Id. at 477.

¹⁹414 Mich 413; 326 NW 372.

conclusive presumption as far as the constitutional inquiry is concerned. Both flow from the Michigan Legislature's exercise of its legislative authority. Likewise, from a constitutional standpoint, there should be no practical difference between "compliance with FDA standards" and "FDA approval." Each constitutes an extrinsic standard having independent existence.

**5. THE INCORPORATION OF FDA APPROVAL AS
AN EXTRINSIC STANDARD IN STATE STATUTES
IS NEITHER EXTRAORDINARY NOR IMPERMISSIBLE**

The apparent notion of plaintiffs, Wayne County Circuit Court, and the Court of Appeals that incorporation of FDA approval into a state statute somehow constitutes an extraordinary and impermissible delegation of legislative authority, cannot withstand measurement against actual practice in Michigan or other states.

Outside the area of product liability, Michigan statutes are replete with the incorporation of FDA approval as an appropriate extrinsic standard. MCL 333.7216(1)(f); MSA 14.15(7220)(1)(f), for instance, pertaining to controlled substances, includes in schedule 3 the words "suppository dosage form... approved by the food and drug administration for marketing only as a suppository." MCL 333.7220(1)(c)(ii)(A); MSA 14.15(7220)(1)(c)(ii)(A), provides similarly with regard to schedule 5 of controlled substances. See also: MCL 333.21054(b); MSA 14.15(21054b) ("health maintenance organization[s] shall provide coverage in each group and individual contract for a federal food and drug administration approved drug"); MCL 550.1416a; MSA 24.660(416a) (requiring a health care corporation to provide coverage for FDA-approved drugs used in anticoplastic therapy); MCL 500.3406e; MSA 24.13406(5) (requiring a health insurer to provide coverage "for any federal food and drug administration approved drug").

Numerous other states likewise have statutes incorporating FDA approval as an extrinsic standard. The Official Code of Georgia § 16-13-4 (2001), for example, makes it a felony to sell a controlled substance or dangerous drug. Subsection (a) provides as follows:

(a) No controlled substance or dangerous drug shall be sold for dispensing unless the controlled substance, as defined in Code Section 16-13-21, or the dangerous drug, as defined in Code Section 16-13-71:

(1) Is approved by the Food and Drug Administration for resale;

(2) Has a new approved drug application number (known as an NDA number) unless excepted by the Food and Drug Administration; or

(3) Has an approved abbreviated new drug application number (known as an ANDA number) unless excepted by the Food and Drug Administration.²⁰

²⁰For a further sampling of other statutes incorporating FDA approval as an extrinsic standard, see: Code of Ala[bama] § 20-1-28 (sweetener for soda must be FDA approved); Alaska Stat § 23.10.645 (drug testing methods used on employees must be FDA-approved); Cal[ifornia] Bus & Prof Code § 2259(e)(3) (information given by doctors regarding silicone breast implants must be FDA-approved); C[olorado]. R.S. 18-9-207(2)(b) (drugs for livestock must be FDA-approved); 16 Del[aware]. C. 3003B(C) ("prescription drugs" are those approved by the FDA); H[awaii] RS § 452-1 (massage apparatus must be approved by the FDA); Burns Ind[iana]. Code Ann § 35-42-1-8 (2001) (home HIV kits must be approved by the FDA); 38 M[aine]. R.S. § 1661-A (FDA-approved drugs are exempt from state regulations regarding mercury); M[aryland] Cts & Jud Proc Code Ann § 5-629(b) (a person lawfully administering FDA-approved drug is not liable for adverse effects of drug); Mass[achusetts] Ann Laws ch 176G, § 40 (scope of mandatory contraception insurance benefits defined by FDA-approved contraceptive methods); Minn[esota] Stat § 152.125, subd 3(4) (statute governing treatment of intractable pain does not apply to the prescription of non-FDA-approved drugs); M[iss]o[uri] Rev Stat § 376.1199, subd 1(4) (defining "contraceptive" as FDA-approved contraceptives); Mont[ana] Code Ann, § 50-6-601(1)(a) statute regulating defibrillators applies only to FDA-approved defibrillators); Neb[raska] Rev Stat § 71-356.05 (defining "electrolysis," in part, as procedure with FDA-approval); Nev[ada] Rev Stat § 639.2597 (generic drugs must be FDA-approved); N[ew] Y[ork] Educ Law § 7101-a(10)(b) (requiring optometrists to prescribe FDA-approved drugs); Ohio Rev Code Ann § 2925.06 (prohibiting prescription of non-FDA-approved anabolic steroids); Tenn[essee] Code Ann § 53-14-102 (exempting FDA-approved research from provisions governing prescription drugs); Tex[as] Health & Safety Code § 431.02(z) (prohibiting the sale of non-FDA-approved HIV self-testing kits); V[ermon]t Stat Ann § 4601(4) (defining "generic drug" by reference to FDA's "Orange Book" of approved drug products); W[est] V[irginia] Code § 16-4-24 (exempting FDA-approved over-the-counter drugs from regulatory provision).

Challenges to such statutes on the ground of unconstitutional delegation of legislative authority, have routinely failed. See: *State v Kellogg*, 98 Idaho 541; 568 P2d 514 (1977), and the cases listed there.

**6. SECTION 2946(5) WAS A KEY PART OF THE
LEGISLATURE'S REFORM OF PRODUCT
LIABILITY LAW IN MICHIGAN, AND AN
APPROPRIATE EXERCISE OF LEGISLATIVE
AUTHORITY.**

Section 2946(5) - Public Acts 1995, No. 249 - was a significant component of the Legislature's reform of product liability law in Michigan. It grew out of the same kinds of concerns as those voiced by various commentators and the American Law Institute. 1955 PA 249 had its origin in SB 344 and HB 4508.

The Senate Fiscal Agency Bill Analysis on SB 344 noted the following basis for the legislation:

. . . According to many, over the past several years there has been an explosion of product liability litigation, resulting in unfair and excessive judgments against manufacturers and sellers, bankruptcies, reduced capacity of firms to compete internationally, curtailed innovation, reduced funding for research, higher consumer costs, and unaffordable or unavailable casualty insurance.

. . .

In Congress and state Legislatures, a number of proposals have been advanced to reduce manufacturers and sellers' exposure to liability.

SFA Bill Analysis, SB 344 (8/25/95) at 1.

Another supporting argument was that the bill would address the excesses of tort law, especially in the product liability field where, according to an article in *Business Week*, each year

over \$100 billion flows through the liability system from companies to lawyers and claimants. It was argued that product liability litigation not only threatens the financial viability of many enterprises, but also adds substantially to the cost and unavailability of many goods and services. *Id.* at 10. Further, it was argued that the product liability law would bolster Michigan's economy:

There is reason to believe that these reforms will, in fact, improve the economic climate in Michigan.

Id. at 13.

Proponents of the bill contended that the determinations of expert agencies, rather than those of lay juries, should govern the question of whether a particular product or drug is defective:

It is unfair to deem a product defective when it conforms to all government standards, especially if the product has been tested under the oversight of a Federal or state agency. These standards are promulgated after intense public scrutiny, expert evaluation, and thorough product evaluation. Lay jurors should not be allowed to second-guess a standard that has been developed by government experts.

Id. at 9-10 (emphasis supplied).

The final result of this process - Section 2946(5) - provides as follows:

(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

This statute delegates nothing to the FDA. Rather it uses the extrinsic standard of FDA approval to define the limits of product liability (i.e., the standard of care) for manufacturers and sellers of drugs in Michigan. Moreover the statute provides for the possibilities of intentional withholding or misrepresentation of information, and for bribery, excepting those situations from the statute's application.

The Legislature could have gone much further. It could, for instance, have abolished product liability actions altogether. Const 1963, art 3 § 7. Upholding the constitutionality of the expert witness qualification statute, this Court said in *McDougall*:

... because the Legislature is authorized to change a common-law cause of action or abolish it altogether, *O'Brien v Hazelett & Erdal*, 410 Mich 1, 15; 299 NW2d 336 (1980), it necessarily has the ability to 'circumscribe those qualified to give the requisite proofs to establish the elements of the cause of action'.... The applicable standard of care is an essential element in a medical malpractice action.... Section 2169 essentially modifies that element.

461 Mich at 36 (internal citations omitted). See also: *Dyke v Richard*, 390 Mich 739, 745 (1973) ("A statute which expressly extinguishes a common law right may be regarded as a proper exercise of legislative authority."). Instead, of abolishment, though, the Legislature, through the exercise of its legislative authority, simply limited product liability actions against drug

manufacturers and sellers in certain specific circumstances set forth in the statute. What the Legislature could abolish, it could certainly limit.

II. IT WAS ERROR FOR THE COURT OF APPEALS TO HOLD THAT PLAINTIFFS OVERCAME THE STRONG PRESUMPTION OF CONSTITUTIONALITY ATTACHING TO SECTION 2946(5).

A. THE COURT OF APPEALS RECOGNIZED, BUT THEN IGNORED THE STRONG PRESUMPTION OF CONSTITUTIONALITY ATTACHING TO SECTION 2946(5).

The Court of Appeals in the instant case properly noted the presumption of a statute's constitutionality, stating that "statutes are presumed to be constitutional, and courts have a duty to construe a statute as constitutional unless its unconstitutionality is clearly apparent"; that the "party asserting the constitutional challenge has the burden of proving the law's invalidity"; and that a "party challenging the facial constitutionality of a statute must establish that no circumstances exist under which it would be valid." Opinion, p. 7. Apart from noting the presumption, however, the Court of Appeals appears to have ignored it. This Court will look in vain for any application of the presumption in the Court of Appeals' opinion. Rather than follow the presumption, the Court of Appeals resorted to dubious theories extracted from cases which either do not stand for the extracted theories or have no application whatsoever.

B. LIKE THE WAYNE COUNTY CIRCUIT COURT, THE COURT OF APPEALS ERRED IN ITS RELIANCE UPON THE *COFFMAN* AND THE *COLONY TOWN CLUB* CASES.

Both the Wayne County Circuit Court and the Court of Appeals looked to and relied upon *Coffman v State Board of Examiners*, 331 Mich, 582; 50 NW2d 322 (1951) and *Colony Town Club v Michigan Unemployment Compensation Comm'n*, 301 Mich 107; 3 NW2d 28 (1942). Each court emphasized and quoted the following language from *Coffman*: "The Legislature is prohibited by the Constitution from delegating legislative powers to non-Michigan governmental agencies . . . or to private individuals or associations." The quoted language was dictum having nothing to do with the decision in that case and, as such, having nothing to do with the present matter. In *Coffman*, the plaintiff sought to compel the Michigan Board of Examiners in Optometry to permit him to sit for an examination. The Michigan Board required applicants to be graduates of four-year colleges or universities approved by the Board, and plaintiff had attended such a college.²¹ The Board required four years of college through its rules but the enabling statute did not.

The *Coffman* Court denied the Writ of Mandamus finding that the plaintiff's right to practice optometry was a privilege granted by the State and was subject to the statutory law and reasonable and proper rules of the Board, and held that the Board did not abuse its discretion. The statute allegedly held unconstitutional in *Coffman* was not relevant to the issues before the Court since its requirements had not been adopted as part of the Board's rules. It was not used as

²¹ The portion of the statute rejected by the Court referenced the ratings of optometric schools and colleges by a private association. It required a school rated as class A or class B by the International Association of Boards of Examiners in Optometry.

a reason for denying plaintiff's application and it was also neither contested nor decided in an adversary setting – the parties apparently accepted the attorney general's opinion cited by the Court.

Such dictum is not a proper basis for declaring an act of the Michigan Legislature to be unconstitutional. The Michigan Supreme Court has left no doubt that “statements and comments in an opinion concerning some rule of law or legal proposition not necessarily involved nor essential to determination of the case in hand are, however illuminating, but obiter dicta and lack the force of an adjudication.” *Donajkowski v Alpena Power Co*, 460 Mich 243, 262, n 18; 596 NW2d 574 (1999), citing *Hett v Duffy*, 346 Mich 456; 78 NW2d 284 (1956) (emphasis supplied). In fact, even if *Coffman* were applicable, there is an analogy between what the Court approved in *Coffman* and what is at issue here, i.e., in *Coffman*, a school of optometry must graduate an individual before the individual can take the optometry examination, while in the present matter, the FDA must approve a drug as safe and effective before the regulatory compliance defense can be asserted. The FDA in the present matter is no more performing a legislative function than is the optometry school in *Coffman*, and certainly no one suggests that reliance on the optometry school's graduation was an unconstitutional delegation of legislative power.

The trial court's reliance on *Colony Town Club* was similarly misplaced. In *Colony Town Club*, the Michigan statute at issue incorporated by reference the definition of “employment” used in the federal Social Security Act, i.e., the same standard used under federal law was embodied in the Michigan statute. The appellant argued that in construing the meaning of “employment” under the Michigan statute, the Michigan courts were bound by the IRS's

construction of “employment” under the federal statute. This Court rejected that argument, observing in dictum and as hypothetical supposition that the Michigan statute “if given the construction claimed for it by appellant, is unconstitutional in that it attempts to delegate to a Federal agency the final decision regarding the interpretation and construction to be placed on a State statute.” 301 Mich at 113.

The instant case is totally different from the hypothetical supposition in *Colony Town Club*. Section 2946(5) does not delegate to a federal agency the final decision regarding interpretation and construction to be placed upon a state statute, but rather uses an extrinsic standard which has independent significance - FDA approval - to define the standard of care in certain product liability actions as described in the statute. Nothing in *Coffman* or *Colony Town Club* can be reasonably read to render this an unconstitutional delegation of Legislative authority.

**C. THE COURT OF APPEALS’ RELIANCE
ON THE *DEARBORN INDEPENDENT*
AND THE *RADECKI* CASES IS LIKE-
WISE MISPLACED.**

From *Dearborn Independent, Inc v City of Dearborn*, 331 Mich 447; 49 NW2d 370 (1951) and *Radecki v Director of Bureau of Worker’s Disability Compensation*, 208 Mich App 19; 526 NW2d 611 (1994), the Court of Appeals extracted a distinction “between reference to existing and potential future legislation or agency standards.” Opinion, p. 9.

Whatever merits this distinction might possess in the abstract or in another context, it has no application here. Section 2946(5) is not a reference statute, that is to say, it does not incorporate a standard from a non-Michigan jurisdiction into Michigan law to be applied in Michigan courts. Under Section 2946(5), certain legal consequences result from FDA approval.

It is the fact of FDA approval that governs, a fact that does not change, thus obviating any conceivable concern over "reference to potential future legislation."

Furthermore, even if Section 2946(5) were a reference statute, which it is not, the consequence would not be a finding of unconstitutionality because of supposed "unconstitutional delegation of legislative authority." The very quote taken by the Court of Appeals from *Radecki* says "[s]tatutes that incorporate existing federal statutes by reference are valid and constitutional." Opinion, p. 10. When a Michigan statute does adopt by reference a federal statute that is subsequently amended though the Michigan statute remains unchanged, the quote from *Radecki* continues, the sole consequence is that the "courts are constitutionally required to construe the statute as continuing to refer to the original federal enactment before amendment." Id. The Court of Appeals even went on to interpret *Radecki* as standing for the principle that:

... in enacting a new statute the Michigan Legislature may rely on and incorporate by reference standards established by its sister states and the federal government, but, as applicable to Michigan, those standards may only evolve by action of the Michigan Legislature.

Id. Thus, both *Radecki* and the Court of Appeals' interpretation speak to a frozen-in-time effect for reference statutes, not their unconstitutionality.

Yet, the next paragraph of the Court of Appeals' opinion begins with this sentence: "Given these distinctions and parameters, we conclude that MCL 600.2946(5) operates as an unconstitutional delegation of legislative authority." Opinion, p. 10. Thus, the Court of Appeals relied at least in part on *Radecki* and, by implication, *Dearborn Independent*, to support a finding of unconstitutionality, though the two cases stand for an opposite outcome.

**D. THE COURT OF APPEALS ACKNOWLEDGED
THE DOCTRINE OF INDEPENDENT SIGNIFI-
CANCE, BUT ADDED TO IT AN INSUPPORTABLE
QUALIFICATION.**

At page 11 of its Opinion, the Court of Appeals states that "[a]ssimilation of standards adopted for a purpose separate from the incorporating legislation, and having independent significance, presents no problem." The statement is in accord with settled Michigan law.

This Court held as follows in *Tribbett v Marcellus*, 294 Mich 607, 615; 293 NW 872 (1940):

While the legislature cannot delegate its power to make a law, nevertheless it can enact a law to delegate a power to determine a fact or state of things upon which the application of the law depends. *Field v Clark*, 143 U.S. 649 (12 Sup. Ct. 495). Where it is difficult or impracticable to lay down a definite comprehensive rule for the application of a statute, the legislature may vest discretionary power in courts or public officials for the determination of whether the law applies in a particular instance.

In *Michigan Baptist Homes and Development Co v City of Ann Arbor*, 55 Mich App 725; 223 NW2d 324 (1974), *aff'd*, 396 Mich 660; 242 NW2d 749 (1976), the Court of Appeals, affirmed by this Court, held the following:

Plaintiff claims that the Michigan Legislature, by limiting the exemption provided by § 7d(1) of the General Property Tax Act to nonprofit corporations which have obtained financing under § 202 of the National Housing Act, has made the exemption dependent of action by the Secretary of Housing and Urban Development, and that limiting the exemption in this manner is invalid as an unconstitutional delegation of power to a Federal official to decide who receives the exemption. We disagree.

The Federal official does not make a determination as to who shall receive the exemption. He merely determines which nonprofit corporations are eligible to receive Federal financing under § 202....

55 Mich App at 737.

As defendants-appellants detail in their Application for Leave to Appeal, dated December 21, 2001, the assimilation of facts with independent significance is a common legislative practice in Michigan. Moreover, as defendants-appellants' application further demonstrates, courts across the country routinely uphold the constitutionality of statutes that assimilate determinations of non-legislative bodies under the doctrine of independent significance.

Given all of this, one could reasonably conclude that Section 2946(5) must pass constitutional muster by virtue of the doctrine of independent significance. The Michigan Legislature recognized that the FDA had the expertise and resources to determine the safety and efficacy of prescription pharmaceuticals, and concluded that FDA approval - which has a significance independent of Michigan law - constitutes an appropriate basis for determining the standard of care owed by drug manufacturers and sellers. Such a legislative determination is at the heart of lawmaking.

Unfortunately the Court of Appeals added a qualification to its acknowledgment of the independent significance doctrine. For the Court of Appeals, the doctrine presents no problem "if the standards are established and essentially unchanging." Immediately upon stating this qualification, the Court of Appeals found it necessary to append footnote 7 to page 11 of its opinion because *Michigan Baptist Homes*, as the Court of Appeals also acknowledged, involved "varying determinations... made over time by [a] federal official." So to its already rarefied qualification, the Court of Appeals added this further rarefaction:

... it is clear that to the extent those determinations would trigger the operation of the Michigan statute, the variations would all exist within that intended special category. Thus, the high limit of the special category was established at the time the Legislature acted and the Legislature could be confident

that such limit would remain unchanged regardless of the federal official's decision making.

Opinion, p. 11, fn. 7.

The exact meaning of this language seems anything but clear. It may well support the constitutionality of Section 2946(a). For in establishing FDA approval as the trigger for operation of Section 2946(a), could it not be said that the Legislature intended and provided for the creation of a special category of defendants in product liability actions which is to be granted the benefit of the regulatory compliance defense? That being so, does it not follow that even if varying determinations could be made over time by the FDA, it is clear that to the extent those determinations would trigger the operations of Section 2946(5), the variations would all exist within that intended special category?

**E. THE COURT OF APPEALS ADVANCED
NO BASIS IN ITS OPINION SUFFICIENT
TO OVERCOME THE STRONG PRESUMP-
TION OF CONSTITUTIONALITY ATTACH-
ING TO SECTION 2946(5).**

No one disputes - not plaintiffs, not Wayne County Circuit Court, not the Court of Appeals - that statutes are presumed to be constitutional, that courts have a duty to construe a statute as constitutional unless its unconstitutionality is clearly apparent, and that a party challenging the facial constitutionality of a statute must establish that no circumstances exist under which it would be valid. Opinion, p. 7.

In finding Section 2946(5) unconstitutional - despite the strong presumption of constitutionality attaching to it - the Court of Appeals relied on the *Coffman*, *Colony Town Club*, *Dearborn Independent*, *Radecki*, and *Michigan Baptist Homes* cases. None of these cases upon

analysis, however, require or even support the Court of Appeals' finding. Each case can be reasonably read either as supportive of Section 2946(5)'s constitutionality or as inapplicable to the present inquiry. The Court of Appeals' reading of these cases could at best be described as tenuous if not outright mistaken.

Surely, the strong presumption of constitutionality which attaches to Section 2946(5) - as it attaches to every statute - cannot be overcome by such strained interpretation and misreading. The exercise of legislative authority does not so easily or lightly yield.

CONCLUSION AND RELIEF REQUESTED

Instead of viewing Section 2946(5) as a permissible adoption of an extrinsic standard defining the parameters of the standard of care owed by drug manufacturers and sellers, the Court of Appeals erroneously declared the statute unconstitutional. In so doing, the Court of Appeals ignored the strong presumption of constitutionality supporting Section 2946(5), and overlooked case law where statutes containing delegations to outside agencies have been upheld. Moreover, the case law on which the Court of Appeals' did rely is either inapplicable to the present matter or supportive of constitutionality.

For all of the foregoing reasons and the reasons presented to the Court by the Defendants/Appellants and other *amici* supporting Defendants-Appellants' appeal, your *amicus curiae*, The Product Liability Advisory Council, Inc., requests that this Court grant the appeal from the Court of Appeals' decision and reverse that decision.

Respectfully submitted,

CLARK HILL PLC

By: James E. Brenner
James E. Brenner (P11178)
Paul C. Smith (P55608)

500 Woodward Avenue, Suite 3500
Detroit, MI 48226-3435
(313) 965-8300

Hugh F. Young, Jr., Esq.
Product Liability Advisory Council, Inc.
1850 Centennial Park Drive, Suite 510
Reston, VA 20191
(703) 264-5300
Of Counsel

Attorneys for The Product Liability
Advisory Council, *Amicus Curiae*

Date: August 22, 2002

A

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